JUN - 6 2001

K003937

SUMMARY OF SAFETY

Date Prepared: 2 May 2001

Product name: CPR EZY ™ MASK and CPR EZY ™ PAD

Company: **Medteq Innovations Pty Ltd**

Contact Person: Eduardo March – AAC Consulting Group Inc.
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765 USA
PH: 301 838 3120 FAX: 301 838 3182

- Predicate device for equivalence: CPRplus™ (K926333) - Kelly Medical Products Inc. Princeton, New Jersey, U.S.A.
- Device Classification: Unclassified, Product Code: 74 LIX – CPR Aid
- Intended Use: To assist rescuers to effectively perform full cardiopulmonary resuscitation including airway clearing, breathing and circulation.

CPR Ezy Description:

The CPR EZy is composed of two components, Mask and Pad. The CPR EZY ™ Mask is a patented facemask with the following features and benefits. The Mask blocks the patient's nose to improve the flow of air to the mouth and lungs. It has a one-way valve to prevent vomit, blood and mucus coming in contact with the rescuer. The CPR EZY ™ Pad is an electromechanical, pressure-sensing unit providing rescuers with a visual indication of the amount of force required for each chest compression and the rate at which these compressions should be performed. By observing the light displayed on the Pad during chest compressions, the rescuer is able to judge and apply the proper amount of force for subsequent compressions.

The CPR EZY ™ is an electromechanical device with similar technological characteristics as its predicate device providing an

audible indication of the desired frequency of chest compression and a display of the level of compression force used during CPR.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Eduardo March
Medteq Innovations Pty Ltd.
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765

Re: K003937
CPR Ezy Mask and CPR Ezy Pad
Regulation Number: Unclassified
Regulatory Class: Unclassified
Product Code: 74 LIX
Dated: April 4, 2001
Received: April 6, 2001

Dear Mr. March:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

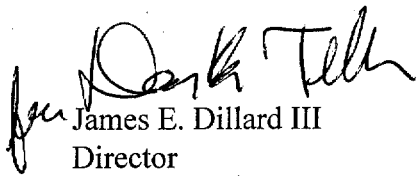
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003937

DEVICE NAME: CPR Ezy MASK™ AND CPR Ezy PAD™

INDICATIONS FOR USE:

To assist rescuers to effectively perform full cardiopulmonary resuscitation including airway clearing, breathing and circulation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluations (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003937

Prescription Use _____ OR Over-the Counter Use X
(Per 21 CFR 801.109)